RECORD AND BRIEFS

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Supreme Court of the United States

OIL STATES ENERGY SERVICES, LLC,

Petitioner,

v.

GREENE'S ENERGY GROUP, LLC, *et al.*,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF OF *AMICUS CURIAE* SHIRE PHARMACEUTICALS LLC IN SUPPORT OF NEITHER PARTY

JAMES HARRINGTON
Senior Vice President and Chief Intellectual Property Counsel
SHIRE PHARMACEUTICALS LLC
95 Hayden Avenue
Lexington, MA 02421

EDGAR H. HAUG
Counsel of Record
NICHOLAS F. GIOVE
RICHARD F. KURZ
JONATHAN A. HERSTOFF
HAUG PARTNERS LLP
745 Fifth Avenue
New York, NY 10151
(212) 588-0800
ehaug@haugpartners.com

Counsel for Amicus Curiae

275293

COUNSEL PRESS

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RULE 29.6 STATEMENT

Shire Pharmaceuticals LLC is an indirectly owned subsidiary of Shire plc, a publicly held company.

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Shire Pharmaceuticals LLC ("Shire") submits this brief as amicus curiae in support of neither party.[1]

INTEREST OF THE *AMICUS CURIAE*

Shire is a global biotechnology company that discovers, develops, and markets medicines for the treatment of rare and specialty diseases in select therapeutic areas, which include hematology, ophthalmics, immunology, internal medicine, neuroscience, genetic diseases, and oncology. Rare diseases, most of which are genetic and are present throughout a person's entire life, pose a significant medical and economic burden for patients, communities, and healthcare systems. There are more than 7,000 known rare diseases impacting 350 million people worldwide. Millions more have specialized conditions. An untold number of people, nearly half of whom are children, struggle with health challenges that, in many cases, cannot be adequately addressed today. Continued innovation by Shire and others in the biotechnology industry is vital for improving such peoples' lives.

Shire champions underserved patient communities by focusing its product pipeline on the development of new therapies for patients with unmet needs to make meaningful differences in their lives. Shire's

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1. All parties have consented to the filing of this amicus brief pursuant to Supreme Court Rule 37.3(a). The parties' letters of consent have been filed with the Clerk of the Court. Pursuant to Supreme Court Rule 37.6, Shire states that this brief was written by Shire, and was produced and funded exclusively by Shire and its counsel. No party or counsel for a party was involved in preparing this brief or made a monetary contribution intended to fund the preparation or submission of this brief.

strategy requires enormous investments in research and development ("R&D") and in business development through acquiring and in-licensing innovative products and technologies. As is generally true for biotechnology industry innovators, Shire's strategy relies on patent rights to secure these investments.

Shire has no direct stake in the result of this case. However, Shire and related companies are and have been parties to numerous *inter partes* review ("IPR") proceedings.

SUMMARY OF ARGUMENT

This case is about an issue of critical importance to our nation's innovation-driven society. The United States economy increasingly relies on innovation and the intellectual property rights that protect such innovation. Perhaps nowhere is this more true than the biotechnology industry, where enormous investments are necessary to invent and develop new life-saving drugs, and to seek FDA approval to bring them to market. Through patents, companies have long been able to secure their investments with exclusive rights that could not be taken away without the safeguards of due process provided by Article III courts. But with IPRs, Congress destabilized patent rights by allowing the government to extinguish patents in administrative proceedings lacking Article III protections.

The statutory design of IPRs violates the Constitution. In IPRs, patents—which are vested private property rights—are extinguished in adversarial proceedings that are designed to lack Article III safeguards against

political influence. Indeed, the statute all but ensures that such proceedings will be subject to executive-branch policy. Thus, with IPRs the strength of patents that Shire and other companies rely on to build businesses may change with the shifting political winds in Washington, D.C.

By design, IPRs lack Article III protections. IPR proceedings are conducted by administrative patent judges who sit on the Patent Trial and Appeal Board ("PTAB") in the U.S. Patent and Trademark Office ("PTO"). The PTAB is controlled by the PTO Director, who is a political appointee with a statutory duty to implement executive-branch policy. The administrative patent judges that staff the PTAB are PTO employees who report to and are compensated by the Director. Any third party may petition the Director to institute an IPR, regardless of whether they have Article III case-or-controversy standing. Once petitioned, the Director has discretion to decide whether to institute an IPR, and the institution decision is final and nonappealable. For each IPR, the Director also designates the specific administrative patent judges who will preside over the proceeding. Furthermore, if the Director is dissatisfied with a panel's earlier decision, the PTO can expand the panel in order to "secure and maintain uniformity for the Board's decisions," and the reconstituted panel may set then aside the earlier decision. *See* Section II.B.1, *supra*. And during the proceedings, a "fluid, case-based interpretation by the PTO of its own regulations" is used for substantive and procedural issues. *See id.* Thus, IPRs extinguish vested private property rights in a tribunal that is statutorily designed to lack Article III protections against political influence.

The PTAB's final written decision in an IPR may be appealed to the U.S. Court of Appeals for the Federal Circuit—but such appeals are rarely successful because the PTAB is afforded a very deferential standard of review on appeal. Its fluid, case-based interpretations of its regulations are set aside only when arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. And its factual findings are overturned only when unsupported by substantial evidence. Moreover, the Director is empowered to intervene and take any position on appeal. Under these circumstances, it is unsurprising that nearly half of all appeals have been summarily affirmed by the Federal Circuit without opinion, and the PTAB has been reversed or vacated on every issue a mere 10% of the time.

By designing IPRs in this way, Congress improperly gave the executive branch the ability to extinguish vested private property rights at the request of third parties in proceedings that are subject to political influence. This case provides the Court with an important opportunity to clarify that, under the Constitution, vested private property rights secured by patents cannot be extinguished in administrative forums that lack Article III safeguards.

ARGUMENT

I. Patent Rights Are Vital for Biotechnology Companies that Research and Develop New Drugs

A. Robust Patent Protection Is Crucial to the Operation of Innovative Biotechnology Companies

As discussed in detail above, Shire is a global biotechnology company that discovers, develops, and markets medicines for the treatment of rare and specialty diseases. The biotechnology industry is built on innovation. Many treatment options that are available today were only dreams just a handful of years ago. Despite this, there are an untold number of people with unmet needs for the treatment of debilitating diseases or conditions—all too often, satisfactory treatment options have yet to be developed or discovered. Improving such people's lives depends on continued innovation by Shire and others in the biotechnology industry. Doing so requires substantial and prolonged investments, because the drug development and approval process takes years and few drugs or treatments in development are ever successfully marketed.

Shire relies on patent rights to secure these investments, as do other biotechnology innovators. The Constitution includes an express clause allowing for the creation of patent laws to encourage such innovation "by ***securing*** for limited times to . . . inventors ***the exclusive right*** to their . . . discoveries." U.S. Const. art. I, § 8, cl. 8 (emphasis added). Securing exclusive rights to discoveries is critically important in the biotechnology industry. Developing new drugs is extraordinarily expensive—

studies estimate that the average cost of developing a drug that receives FDA approval is between $1.3 billion and $4 billion.[2] R&D takes years and failure rates are significant. Thus, only a small percentage of drug candidates are ever successfully developed into FDA-approved products. It would be difficult, if not impossible, to justify such investments if inventions could be copied and exploited by third parties before innovators have had a reasonable opportunity to recoup their investments. Thus, "[t]he patent laws 'promote the Progress of Science and useful Arts' by rewarding innovation with a temporary monopoly." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 730 (2002) (quoting U.S. Const. art. I, § 8, cl. 8). In return for this "property right," the patent laws "require inventors to describe their work in full, clear, concise, and exact terms," which enables the public's efficient investment in further innovation. *Id.* at 730-31 (quotation omitted). By doing so, the patent laws maintain a "delicate balance" between "inventors, who rely on the promise of the law to bring the invention forth, and the public, which should be encouraged to pursue innovations, creations, and new ideas beyond the inventor's exclusive rights." *Id.* at 731.

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2. *E.g.*, Matthew Herper, *The Truly Staggering Cost of Inventing New Drugs*, Forbes (Feb. 10, 2012, 7:41 AM), https://www.forbes.com/sites/matthewherper/2012/02/10/the-truly-staggering-cost-of-inventing-new-drugs/#28666bed4a94 (last visited Aug. 30, 2017) (citing various studies); *see also* Tufts Center for the Study of Drug Development, *Tufts CSDD Assessment of Cost to Develop and Win Marketing Approval for a New Drug Now Published* (Mar. 10, 2016), http://csdd.tufts.edu/news/complete_story/tufts_csdd_rd_cost_study_now_published (last visited Aug. 30, 2017) (discussing a study that estimated that the average cost to develop and gain marketing approval for a new drug was $2.558 billion).

IPRs upset this delicate balance by giving the government a means to extinguish vested private property rights in adversarial proceedings initiated by third parties, which are conducted in tribunals that are statutorily designed to be subject to political influence. This creates a disincentive for making investments in new discoveries and technologies because the foundation for such investments is destabilized. Further, IPRs upset this balance only after the inventor upholds the requirement to fully and clearly describe the invention for the public's benefit. IPRs thus encourage inventors to maintain inventions as trade secrets or otherwise seek to withhold clear descriptions of inventions from the public, which may lessen future innovation. IPRs harm the very innovation that the patent laws are meant to promote.

B. Once Granted by the PTO, a Patent Is a Vested Private Property Right, and Extinguishment of that Right Should Only Occur in Courts Having Article III Protections

When the government extinguishes a granted patent, it takes a patent owner's exclusive vested private property right to an invention and gives it to the public. "That a patent is property, protected against appropriation both by individuals and government, has long been settled." *Hartford-Empire Co. v. United States*, 323 U.S. 386, 415 (1945). Once a patent is issued, a "legal right to the monopoly and property it created" becomes "***vested***" in the patent's owner. *Gayler v. Wilder*, 51 U.S. 477, 494 (1851) (emphasis added). "[A]n invention so secured is property in the holder of the patent, and that as such the right of the holder is as much entitled to protection as any other property, during the term for which the

franchise or the exclusive right or privilege is granted." *Cammeyer v. Newton*, 94 U.S. 225, 226 (1876). Patents are "private property; and by the Constitution of the United States, private property cannot be taken for public use without just compensation." *Brown v. Duchesne*, 60 U.S. 183, 197-98 (1856). Furthermore, patents are "a species of property" that "'is as much property as a patent for land.'" *Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank*, 527 U.S. 627, 642 (1999) (quoting *Consol. Fruit-Jar Co. v. Wright*, 94 U.S. 92, 96 (1877)).

Under separation-of-powers principles, extinguishment of vested private property rights must be decided by an Article III tribunal, or at the very least a tribunal with Article III protections—the government cannot take back exclusive property rights at will. "'[A patent] confers upon the patentee an exclusive property in the patented invention which cannot be appropriated or used by the government itself, without just compensation, any more than it can appropriate or use without compensation land which has been patented to a private purchaser.'" *Horne v. Dep't of Agric.*, 135 S. Ct. 2419, 2427 (2015) (quoting *James v. Campbell*, 104 U.S. 356, 358 (1882)). There is a vital distinction between adjudicating: (i) rights to property that belongs to the United States, and (ii) rights to property that vest in an individual after title passes from the government. Once exclusive rights vest by way of an issued patent, the government has no right to the property. Thus, before the government may fairly take that property away from its owner, judicial review with Article III protections is required.

> [M]ost administrative adjudications that were given preclusive effect in Article III

> courts involved quasi-private rights like land grants. . . . And in the context of land grants, this Court recognized that ***once "title had passed from the government," a more complete form of judicial review was available because "the question became one of private right."***

B & B Hardware, Inc. v. Hargis Indus., Inc., 135 S. Ct. 1293, 1317 (2015) (Thomas, J., dissenting) (emphasis added) (quoting *Johnson v. Towsley*, 80 U.S. 72, 87 (1871)).

> Although Congress could authorize executive agencies to dispose of public rights in land—often by means of adjudicating a claimant's qualifications for a land grant under a statute—the United States had to go to the courts if it wished to revoke a patent. . . . That differential treatment reflected the fact that, once "legal title passed out of the United States," the patent "undoubtedly" constituted "a vested right" and consequently could "only be divested according to law."

Wellness Int'l Network, Ltd. v. Sharif, 135 S. Ct. 1932, 1966 (2015) (Thomas, J., dissenting) (some internal alterations, citations, and quotations omitted) (quoting *Johnson*, 80 U.S. at 85).

As the Court has explained, "the relations thus established between the courts and the land department are not only founded on a just view of the duties and powers of each, but are essential to the ends of justice and to a sound administration of the law." *Johnson*, 80 U.S. at 87. "[T]he doctrine of separation of powers is a ***structural***

safeguard . . . ." *Plaut v. Spendthrift Farm, Inc.*, 514 U.S. 211, 239 (1995) (emphasis in original). Patents to inventions are due the same structural safeguards as vested private property rights to land. *Cf. Fla. Prepaid Postsecondary Educ. Expense Bd.*, 527 U.S. at 642. By allowing the executive branch to extinguish vested private property rights in a non-Article III forum, Congress impermissibly violated this Constitutional safeguard.

II. IPR Proceedings Can Unduly Harm Innovator Biotechnology Companies by Extinguishing Their Vested Private Property Rights in a Forum Statutorily Designed to Be Subject to Political Influence

A. Innovative Biotechnology Companies Rely on Stable Patent Rights When Investing in Drug Discovery and Development

Innovative biotechnology companies rely on patent rights to build their businesses. Drug development is very expensive, unpredictable, and time consuming. Many drug candidates that are studied in preclinical and clinical trials are later abandoned due to economic, safety, or efficacy concerns. And even for drugs that achieve FDA approval, it typically takes years to recoup the investments that were made. Stable patent rights provide a critical foundation for these investments.

IPR proceedings are statutorily designed to be subject to political influence. This can unduly harm innovators who depend on patent rights because the strength of patents can be materially altered based on changes in executive-branch policy, including changes that occur when one

presidential administration transitions to another, new personnel appointments are made, and new policies are promulgated. For example, as demonstrated by the recent presidential election, different administrations may have starkly different policy objectives. Accordingly, it is particularly concerning that IPRs permit the extinguishment of vested private property rights by an administrative tribunal that lacks Article III protections against political influence.

To be clear, Shire believes that the Director, administrative patent judges, and other PTAB members undertake their duties with the highest degree of integrity and professionalism. "Not favoritism, nor even corruption, but ***power*** is the object of the separation-of-powers prohibition." *Plaut*, 514 U.S. at 228 (emphasis in original). The statute under which the PTAB operates violates this prohibition because it is designed to unconstitutionally implement executive-branch policy in an adjudicative forum that lacks Article III protections and extinguishes vested private property rights. That the statute is designed to make the PTAB an instrument of executive-branch policy is self-evident. The Director is "appointed by the President, by and with the advice and consent of the Senate," and also "may be removed from office by the President." 35 U.S.C. §§ 3(a)(1), 3(a)(4). Moreover, the PTO "shall be subject to the policy direction of the Secretary of Commerce." 35 U.S.C. § 1(a). The Director's duty is to carry out such policy, since the Director is "responsible for providing policy direction and management supervision for the Office." 35 U.S.C. § 3(a)(2)(A). The Director's policy direction extends to the PTAB, of which the Director is a member. *See* 35 U.S.C. §§ 1(a), 6(a). And, as discussed in more detail in Section III, *infra*,

the PTAB's administrative patent judges work for and are paid by the Director. *See also* 35 U.S.C. §§ 1(a), 3(b)(3)(6), 6(a). Thus, it is to be expected that administrative patent judges are responsible for carrying out the Director's policy because "one who holds his office only during the pleasure of another, cannot be depended upon to maintain an attitude of independence against the latter's will." *Free Enter. Fund v. Pub. Co. Accounting Oversight Bd.*, 561 U.S. 477, 493 (2010) (internal quotation omitted). Furthermore, the PTAB is subject to "Executive order[s], rule[s], regulation[s], or delegation[s] of authority" setting forth administration policy. *See* 35 U.S.C. § 6(a).

Consequently, IPRs extinguish vested private property rights by way of a tribunal that—unlike Article III district courts and many administrative courts, as discussed in Section III below—lacks protections against political influence. "Article III 'not only preserves to litigants their interest in an impartial and independent federal adjudication of claims . . . , but also serves as an inseparable element of the constitutional system of checks and balances." *Wellness Int'l Network*, 135 S. Ct. at 1943 (quoting *Commodity Futures Trading Comm'n v. Schor*, 478 U.S. 833, 850-51 (1986) (internal quotations omitted)). To ensure the impartiality of the judiciary, Article III "provides that the judges of those courts shall hold their offices during good behavior, without diminution of salary." *Stern v. Marshall*, 654 U.S. 462, 469 (2011). Article III safeguards are also provided for proceedings before administrative law judges, such as those at the International Trade Commission ("ITC"). "'Federal administrative law requires that agency adjudication contain[s] many of the same safeguards as are available in the judicial process,'" such as "'[proceedings that] are

conducted before a trier of fact insulated from political influence.'" *Fed. Mar. Comm'n v. S.C. State Ports Auth.*, 535 U.S. 743, 756-57 (2002) (quoting *Butz v. Economou*, 438 U.S. 478, 513 (1978)). In IPRs, however, Article III safeguards against political influence are not present.

B. The Lack of Safeguards Against Political Influence in IPRs Unconstitutionally Destabilizes Innovators' Patent Rights

1. The Design of IPR Proceedings Makes Them Susceptible to Political Influence

Concerns about the lack of safeguards against political influence are not merely speculative. Two Federal Circuit judges recently expressed "concern[] about the PTO's practice of expanding administrative panels to decide requests for rehearing in order to 'secure and maintain uniformity of the Board's decisions.'" *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, ---F.3d----, No. 16-2321, 2017 U.S. App. LEXIS 15923, at *16 (Fed. Cir. Aug. 22, 2017) (Dyk, J., concurring). There, after a three-member administrative patent judge panel denied a joinder request, "'[t]he Acting Chief Judge, acting on behalf of the Director,' . . . expanded the panel from three to five members, and the reconstituted panel set aside the earlier decision." *Id.* at *16-17 (citation omitted). While noting that the "Director represent[ed] that the PTO 'is not directing individual judges to decide cases in a certain way,'" the Federal Circuit judges "question[ed] whether the practice of expanding panels where the PTO is dissatisfied with a panel's earlier decision is the appropriate mechanism of achieving the desired uniformity." *Id.* at *17 (quoting the Director's brief).

The commentary in *Nidec* comports with a previous observation made by the Federal Circuit when discussing the PTAB's predecessor court, which is that since the Director determines the composition of PTAB panels, *see* 35 U.S.C. § 6(c), the Director "may convene a Board panel which he knows or hopes will render the decision he desires, even upon rehearing, as he appears to have done in this case." *In re Alappat*, 33 F.3d 1526, 1535 (Fed. Cir. 1994) (en banc) (discussing the Commissioner's appointment of panel judges to the Board of Patent Appeals and Interferences ("BPAI")), *abrogated on other grounds by In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008) (en banc), *abrogated on other grounds by Bilski v. Kappos*, 561 U.S. 593 (2010); *see also* 35 U.S.C. § 6(a) (equating the BPAI to the PTAB).

Colloquy between Judge Taranto and PTO counsel Mr. Weidenfeller during oral argument in a Federal Circuit case concerning an IPR confirms this practice:

> JUDGE TARANTO: And anytime there has been a seeming other outlier, you've engaged the power to reconfigure the panel so as to get the result you want.
>
> MR. WEIDENFELLER: Yes, your Honor. The --
>
> JUDGE TARANTO: And you don't see a problem with that?
>
> MR. WEIDENFELLER: Your Honor, the Director is trying to ensure that her policy position is being enforced by the panel.

> JUDGE TARANTO: The Director is not given adjudicatory authority, right, under the -- section six of the statute that gives it to the Board?
>
> MR. WEIDENFELLER: Right. To clarify, the Director is a member of the Board, but Your Honor is correct (inaudible).
>
> JUDGE TARANTO: Right, but after the panel is chosen, I'm not sure I see the authority there to -- to engage in case-specific re-adjudication from the Director after the panel has -- has been selected.
>
> MR. WEIDENFELLER: Well, that's correct. Once a panel has been set, it has the adjudicatory authority and the Director has (inaudible).
>
> JUDGE TARANTO: Until in your view it's reset by adding a few members who will come out the other way.
>
> MR. WEIDENFELLER: That's correct, your Honor. We believe that's what (inaudible).

Oral Argument at 47:20-48:25, *Yissum Research Dev. Co. v. Sony Corp.*, No. 15-1343 (Fed. Cir. Dec. 7, 2015), *http://oralarguments.cafc.uscourts.gov/default.aspx?fl=2015-1343.mp3.*[3]

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3. *See also* Appendix at 1, Appx1011-13, *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, No. 16-2321 (Fed. Cir. Feb. 2. 2017), ECF No. 58-2 (showing Mr. Weidenfeller as a PTO counsel, and transcribing testimony quoted above).

In IPRs, the Director has other ways to conform PTAB decisions to executive-branch policy. IPRs lack safeguards built into the judicial process, because in addition to not "insulat[ing] [administrative patent] judge[s] from political influence," the PTAB decides procedural and substantive issues on a case-by-case basis, thus giving little weight to "the importance of precedent in resolving controversies." *Cf. Butz*, 438 U.S. at 512 (discussing "safeguards built into the judicial process"). The PTAB is rarely bound by its own precedent when resolving controversies. As of March 31, 2017, the PTAB had issued Final Written Decisions in 1,577 IPR trials, but as of this writing the PTAB has only designated 37 of its decisions as "Precedential," and of these ***only 11*** were from *inter partes* reviews or reexaminations—the remainder were *ex parte* decisions.[4] In lieu of precedential decisions, when interpreting aspects of the statute the PTO follows a practice of using "adjudicative Board decisions . . . , rather than traditional notice and comment rule-making." *Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1306 (Fed. Cir. 2015). This practice extends to such substantive issues as burdens of proof. *Id.*; *see also Medtronic Inc. v. Mirowski Family Ventures, LLC*, 134 S. Ct. 843, 849 (2014) (explaining that "[t]he assignment of the burden of proof is a rule of substantive law" (quotation and citation omitted)). Despite affirming this practice, the Federal Circuit recognized that "[a] fluid, case-based interpretation by the PTO of its own regulations risks leaving interested members of

4. PTO, Patent Trial and Appeal Board Statistics, at 10 (March 31, 2017), https://www.uspto.gov/sites/default/files/documents/AIA%20Statistics_March2017.pdf (last visited Aug. 30, 2017); PTO, List of Precedential Opinions, https://www.uspto.gov/patents-application-process/appealing-patent-decisions/decisions-and-opinions/precedential (last visited Aug. 30, 2017).

the public in a state of uncertainty, without ascertainable standards and adequate notice to comply." *Microsoft*, 789 F.3d at 1307.

In addition, PTAB practices constrain the facts that a party is able to present in IPRs, as compared to Article III district courts. In district courts, litigants have the ability to discover and present evidence in accordance with both the Federal Rules of Civil Procedure and the Federal Rules of Evidence, and may present live testimony and cross-examine witnesses at trial. In contrast, PTAB decisions are made after limited discovery,[5] and IPR litigants are rarely permitted to present live testimony at an oral hearing before the PTAB. *See* 37 C.F.R. § 42.51; PTO, Office Trial Practice Guide, 77 Fed. Reg. 48756, 48768 (Aug. 14, 2012). For example, "a party seeking to submit supplemental information more than one month after the date an IPR is instituted must request authorization to file a motion to submit the information." *Ultratec, Inc. v. Captioncall, LLC*, ---F.3d----, No. 16-1712, 2017 U.S. App. LEXIS 16363, at *8-9 (Fed. Cir. Aug. 28, 2017) (citing 37 C.F.R. § 42.123(b)). Until the PTAB Board authorizes filing such a motion, "'no evidence is permitted to be filed,' and the briefing [for such a request] 'must not include a discussion of the contents or types of the particular documents sought to be entered.'" *Id.* at *4 (quoting PTO Brief). Additionally, Federal Circuit judges have noted that while "[t]he PTO at times refers to the IPR proceedings as a 'trial' . . . [v]ery seldom do

5. The discovery afforded to IPR litigants is generally little more than the rough equivalent of a deposition of any affiant, unless the parties agree to additional discovery or, on motion, the Board chooses to grant additional discovery. 37 C.F.R. § 42.51(b)(1)(ii).

IPR proceedings have the hallmarks of what is typically thought of as a trial." *Id.* at *5 n.2 (citation omitted, quoting PTO Brief). "Live testimony is rare in IPR hearings, which typically last only about an hour . . . [and the Board] makes credibility determinations based only on written declarations." *Id.* at *12. Thus, unlike district court proceedings, the PTAB reaches its decisions on relatively limited and cold records.

2. Any Judicial Oversight of IPRs Is Minimal Because IPR Final Written Decisions Receive Very Deferential Appellate Review and Are Unlikely to Be Overturned

Overturning an IPR decision on appeal is highly unlikely because the PTAB is given a high degree of deference "using the standards set forth in the Administrative Procedure Act, 5 U.S.C. § 706." *See Microsoft*, 795 F.3d at 1306. Under that statute, the Federal Circuit: "set[s] aside actions of the Board that are arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, and set[s] aside factual findings that are unsupported by substantial evidence." *Id.* (internal quotations omitted). Under this standard, as of July 1, 2017, the Federal Circuit has summarily affirmed, without opinion, the PTAB approximately 49.11% of the time. David C. Seastrunk et al., *Federal Circuit PTAB Appeal Statistics – July 1, 2017*, AIABlog (July 18, 2017), http://www.aiablog.com/ptab-stats/federal-circuit-ptab-appeal-statistics-july-1-2017/ (last visited Aug. 30, 2017). Overall, during that time period the PTAB has been affirmed on every issue in 152 (75.62%) of cases, and only reversed or vacated on every issue in 20 (9.95%) cases. *Id.*

With this deferential standard, such an outcome is unsurprising. As one circuit judge explained in a different context, the doctrine of deference to agencies "require[s] us at times to lay aside fairness and our own best judgment and instead bow to the nation's most powerful litigant, the government, for no reason other than that it is the government." *Egan v. Del. River Port Auth.*, 851 F.3d 263, 278 (3d Cir. 2017) (Jordan, J., concurring). "Agencies can make the ground rules and change them in the middle of the game." *Id.* at 281. "When the power to create and interpret and enforce the law is vested in a single branch of government, the risk of arbitrary conduct is high and individual liberty is in jeopardy. An agency can change its statutory interpretation with minimal justification and still be entitled to full deference from Article III courts." *Id.* at 280. Such commentary is relevant for IPRs because the PTO Director: (i) has a statutory responsibility to carry out executive-branch policy, (ii) oversees and controls the pay of PTAB judges, (iii) has a statutory ability to configure case-specific panels to hear IPRs, (iv) expands panels to re-hear issues when dissatisfied with an earlier panel's decision, and (v) has the PTAB use a "fluid, case-based" approach in lieu of precedent when deciding substantive and procedural issues.[6] As a result, from the standpoint of due process, IPR proceedings lack safeguards against political influence offered by Article III courts. *Cf. Caperton v. A.T. Massey Coal Co.*, 556 U.S. 868, 876 (2009) (recognizing that "[a] fair trial in a fair

6. In one recent example, a Federal Circuit panel vacated a PTAB decision, but did so after noting that "the [PTAB] Board's procedures impede meaningful appellate review of the agency decision-making." *Ultratec*, 2017 U.S. App. LEXIS 16363, at *13. Despite these comments, the Federal Circuit panel did not hold that the PTAB's procedures must change. *See generally id.*

tribunal is a basic requirement of due process" (citation omitted)). Furthermore, the PTAB's case-based rules and fact-finding are unlikely to be overturned on appeal.

The Federal Circuit's deference to the PTAB's IPR decisions is especially apparent from its willingness to uphold the PTAB's invalidation of a patent, even after the Federal Circuit previously found the same patent valid following an appeal arising from a district court. In particular, the Federal Circuit concluded that "even if the record [in the IPR and district-court proceedings] were the same," it is acceptable for the PTAB's ruling to diverge from the Federal Circuit's ruling because under the statute the PTAB applies a different burden of proof. *Novartis AG v. Noven Pharm. Inc.*, 853 F.3d 1289, 1294 (Fed. Cir. 2017).[7] The PTAB's authority to effectively undo the decision of an Article III court cannot be squared with this Court's precedent, which has found it unconstitutional for another branch of government to "retroactively command[] the federal courts to reopen final judgments[.]" *Plaut*, 514 U.S. at 219; *see also In re Baxter Int'l, Inc.*, 678 F.3d 1357, 1366-68 (Fed. Cir. 2012) (Newman, J., dissenting) (explaining why the PTO's

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7. Divergent results can occur even when the same parties and patents are at issue in parallel cases. *See, e.g., Ultratec*, 2017 U.S. App. LEXIS 16363, at *2-3 (vacating and remanding a PTAB decision based on evidentiary issues, but explaining that the parties in the case "are currently litigating in both district court and before the [PTAB] Board" and that, while in the district court "the jury found the patents valid and infringed and awarded damages," the district court stayed post-judgment proceedings because "[f]ive months after the verdict, the [PTAB] Board issued final written decisions holding" the challenged patent claims invalid).

ability, in a reexamination proceeding, to undo a district court's validity decision violates this Court's precedents).

The ability of the PTAB to override (and to have preclusive effect over) decisions from Article III courts appears to be unique to the PTAB. Other agencies do not have this power. For example, at the ITC—where, unlike the PTAB, the patent owner voluntarily brings a suit to adjudicate patent rights—the non-Article III tribunal's invalidity ruling does not have preclusive effect for district courts. *Tandon Corp. v. U.S. Int'l Trade Comm'n*, 831 F.2d 1017, 1019 (Fed. Cir. 1987) (concluding that the Federal Circuit's "appellate treatment of decisions of the Commission does not estop fresh consideration by other tribunals"); *Lannom Mfg. Co. v. U.S. Int'l Trade Comm'n*, 799 F.2d 1572, 1577-78 (Fed. Cir. 1986) (noting the legislative history's statement that "[t]he Commission is not, of course, empowered . . . to set aside a patent as being invalid or to render it unenforceable"); *see also Texas Instruments Inc. v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1568-70 (Fed. Cir. 1996) (reaffirming that ITC decisions are not entitled to collateral-estoppel effect upon district courts); *Bio-Tech. Gen. Corp. v. Genentech, Inc.*, 80 F.3d 1553, 1564 (Fed. Cir. 1996) (reaffirming that ITC decisions are not entitled to res judicata effect upon district courts).

Thus, IPRs unconstitutionally extinguish vested private property rights in administrative proceedings that are statutorily designed to be subject to political influence. IPRs unduly harm innovator biotechnology companies by destabilizing patent rights, upon which biotechnology innovators rely to protect investments that are made to invent, develop, and bring to market new life-saving drugs.

III. By Statutory Design, IPRs Lack Article III Procedural Safeguards Against Political Influence Provided to Parties in District Court Judicial Proceedings and Administrative Proceedings Before Administrative Law Judges

"[T]he constitutionality of a given congressional delegation of adjudicative functions to a non-Article III body must be assessed by reference to the purposes underlying the requirements of Article III." *Commodity Futures Trading Comm'n*, 478 U.S. at 847. As relevant here, Article III "safeguard[s] litigants' 'right to have claims decided before judges who are free from potential domination by other branches of government.'" *Id.* at 848 (quoting *United States v. Will*, 449 U.S. 200, 218 (1980)). As discussed in Section II, *supra*, the PTAB is subject to executive-branch political policy, and therefore does not serve the purposes of Article III. Moreover, the PTAB does not have the safeguards of non-Article III tribunals that this Court has upheld in the past.

A. By Statute, the PTAB, Unlike Article III Courts, Is Subject to Control by the Executive Branch

In many relevant respects, the structure of the PTAB differs sharply from that envisioned by Article III.

First, Article III judges enjoy lifetime tenure and cannot have their salary reduced. *Stern*, 564 U.S. at 469. In stark contrast, the PTAB is controlled by the Director (a political appointee), and is staffed by administrative

patent judges who work for the Director.[8] 35 U.S.C. § 1(a) (providing that the PTO exercises "independent control of its . . . personnel decisions and processes"); 35 U.S.C. § 3(a)(1) (specifying that the powers and duties of the PTO "shall be vested in" the Director); 35 U.S.C. § 6(a) (specifying that the PTAB includes the Director, and that the administrative patent judges are appointed by the Secretary of Commerce in consultation with the Director, and providing that the PTAB is subject to Executive orders). Moreover, the Director "may fix the rate of basic pay for the administrative patent judges." 35 U.S.C. § 3(b)(6). The Director is appointed by the President, and may unilaterally be removed from office by the President. 35 U.S.C. § 3(a)(1), (4). This Court has recognized that "one who holds his office only during the pleasure of another, cannot be depended upon to maintain an attitude of independence against the latter's will." *Free Enter. Fund*, 561 U.S. at 493 (citation omitted). Given (i) the Director's direct influence on the PTAB and (ii) the President's indirect influence on the PTAB through the Director, the PTAB—by design—is not protected from influence by the executive branch.

Second, the Director is given broad latitude to decide whether an IPR should be instituted and the scope of any such IPR, and need not institute a proceeding even where the statutory requirements are met. *See* 35 U.S.C. § 314(a). The Director's institution decision is not appealable. 35 U.S.C. § 314(d). The Director is also given the authority to designate each 3-member PTAB panel that decides

8. As will be discussed below, administrative patent judges are ***not*** administrative law judges ("ALJs"), and do not have the same protections against political influence as ALJs do.

the IPR. 35 U.S.C. § 6(a). And when the Director is dissatisfied with a panel's decision, the Director may convene an "expanded" panel, with personally selected judges, to rehear the matter. *See Nidec Motor*, 2017 U.S. Dist. LEXIS, at *17 (Dyk, J., concurring) ("question[ing] whether the practice of expanding panels where the PTO is dissatisfied with a panel's earlier decision is the appropriate mechanism of achieving the desired uniformity" in PTO decisions, yet agreeing to affirm the PTAB's final written decision); *see also* John M. Golden, *Working Without Chevron: The PTO as Prime Mover*, 65 Duke L.J. 1657, 1663 (2016) (discussing the issue of panel-stacking in the PTO).

In contrast, Article III courts do not have such unbridled discretion to choose which cases to hear. Rather, when an Article III court has jurisdiction, "it also has a virtually unflagging obligation . . . to exercise that authority." *Mata v. Lynch*, 135 S. Ct. 2150, 2156 (2015) (internal quotation marks omitted). Therefore, unlike the PTAB, an Article III court is generally not permitted to deny a party access to the court when its jurisdiction is properly invoked, and a party who is wrongly denied access is entitled to appellate review. Nor is an Article III court permitted to "expand" a panel to reach a desired outcome. Even an appeals court (other than the Federal Circuit), with the exception of a hearing or rehearing en banc, is bound by the requirement that "[c]ases and controversies shall be heard and determined by a court or panel of not more than three judges[.]" 28 U.S.C. § 46(c). Although courts of appeals are permitted to sit en banc, this procedure is ordinarily limited to instances where: (1) there has been a lack of uniformity between different panels of the same court, or (2) the case involves a question

of exceptional importance. Fed. R. App. P. 35(a). En banc hearings are not a mechanism to "stack" an appeals panel with selected judges.

Third, by statute, the Director has the discretion to continue the IPR even after the petitioner and patent owner have elected to settle. 35 U.S.C. § 317(a). The Director is also vested with the authority to intervene and defend the PTAB's rulings in any appeal to the Federal Circuit. 35 U.S.C. § 143.[9] In such appeals, the PTO argues that "the Director has statutory authority to take any position in [such] cases." Supp. Br. for Intervenor—Director of the U.S. Patent & Trademark Office at 13, *Knowles Elecs. LLC v. Matal*, No. 16-1954 (Fed. Cir. July 31, 2017), ECF No. 65. Thus, the statutory scheme for IPRs specifically contemplates that the PTO be an interested party. This stands in stark contrast to Article III judges, who are required to be neutral arbiters, and do not have the right to become a party to an appeal from their decisions. Moreover, Article III judges generally have no authority to continue a litigation after the parties have settled. *See generally U.S. Bancorp Mortg. Co. v. Bonner Mall P'ship*, 513 U.S. 18 (1994) (recognizing that settlement of a case generally renders the case moot).

Fourth, the PTAB is not constrained by the Code of Conduct for United States Judges or by any other

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9. The Director's apparently unlimited authority to defend the PTAB's ruling to the Federal Circuit also stands in stark contrast to the rights of the other parties, who do not necessarily have the right to seek judicial review of the PTAB's final written decision. *See Phigenix, Inc. v. ImmunoGen, Inc.*, 845 F.3d 1168, 1176 (Fed. Cir. 2017) (concluding that Phigenix lacked Article III standing to appeal the PTAB's final written decision in an IPR).

similar code of conduct.[10] An Article III judge would almost certainly be disqualified from deciding a case that involves his former client. In contrast, at least two PTAB judges have sat on cases involving their former clients. For example, one PTAB judge was assigned to 17 proceedings involving his former client, beginning only 18 months after the representation terminated.[11]

Fifth, as discussed above in Section II, the PTAB is subject to an exceedingly deferential standard of review. This standard has resulted in the Federal Circuit summarily affirming—without opinion—approximately half of the PTAB's decisions that were appealed to the Federal Circuit. In contrast, although courts of appeals also defer to the factual findings of Article III district courts, such deference is given only after the litigants are provided a broad opportunity to discover and present evidence in accordance with the Federal Rules and given the opportunity to present live testimony at trial. PTAB

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10. *See, e.g.*, Gene Quinn, *USPTO Response to FOIA Confirms There Are No Rules of Judicial Conduct for PTAB Judges*, IP Watchdog (May 31, 2017), http://www.ipwatchdog.com/2017/05/31/uspto-response-foia-confirms-no-rules-judicial-conduct-for-ptab-judges/id=83914/ (last visited Aug. 30, 2017).

11. Gene Quinn & Steve Brachman, *More Conflicts of Interest Surface with Second PTAB Judge*, IP Watchdog (May 7, 2017), http://www.ipwatchdog.com/2017/05/07/more-conflicts-interest-surface-second-ptab-judge/id=83012/ (last visited Aug. 30, 2017); *see also* Gene Quinn, *If PTAB Judges Can Decide Cases Involving Former Defense Clients USPTO Conflict Rules Must Change*, IP Watchdog (May 2, 2017), http://www.ipwatchdog.com/2017/05/02/ptab-judge-former-clients-uspto-conflict-rules/id=82765/ (last visited Aug. 30, 2017) (providing specific identifications of the 17 proceedings).

decisions are made without the same standards for fact-finding.

As can readily be seen from the discussion in Section II, *supra*, the statutory design of IPRs provides for political influence from the executive branch on multiple levels, and does not afford litigants many of the safeguards that are available in an Article III forum. IPRs thus fall far short of the requirements that this Court has imposed for extinguishing a party's vested private property rights.

B. Because the PTAB, by Design, Is Subject to Political Influence, IPRs Do Not Afford Litigants the Same Protections that This Court Has Deemed Important in Upholding the Constitutionality of Other Administrative Tribunals

"'Federal administrative law requires that agency adjudication contain many of the same safeguards as are available in the judicial process,'" such as "'[proceedings that] are conducted before a trier of fact insulated from political influence." *Fed. Mar. Comm'n*, 535 U.S. at 756-57 (quoting *Butz*, 438 U.S. at 513). In addition to lacking the safeguards that are present in an Article III forum (discussed above), IPR proceedings also lack the protections from political influence that are present in other non-Article III forums. Contrary to other non-Article III forums, such as the ITC, which utilize administrative law judges ("ALJs"),[12] the PTAB comprises

12. In the ITC, the litigants are entitled to a hearing in front of the ALJ. 19 C.F.R. § 210.36(a)(1). The hearing "shall be conducted in accordance with the Administrative Procedure Act (i.e., 5 U.S.C. §§ 554 through 556)." 19 C.F.R. § 210.36(d).

administrative patent judges who lack the protections from political influence that ALJs enjoy.

First, as discussed above, administrative patent judges' pay is controlled by the PTO Director. 35 U.S.C. § 3(b)(6). An ALJ's pay, in contrast, is set by statute. 5 U.S.C. § 5372. In particular, the Office of Personnel Management is responsible for setting uniform pay rates that apply to ***all*** ALJs in ***all*** agencies that employ ALJs (5 U.S.C. § 5372(b)(2)), and these pay scales may be adjusted by the President (5 U.S.C. § 5372(b)(4)); *see also* U.S. Off. of Pers. Mgmt., Fact Sheet: Administrative Law Judge Pay System, https://www.opm.gov/policy-data-oversight/pay-leave/pay-administration/fact-sheets/administrative-law-judge-pay-system/ (last visited Aug. 30, 2017). Contrary to the pay of administrative patent judges, the rate of pay for ALJs does not vary from agency to agency and is not subject to a particular Director's discretion.

Second, ALJs enjoy job security and are sheltered from job-performance ratings and performance-related awards or monetary incentives. "An administrative law judge receives a career appointment and is exempt from the probationary period requirements under part 315 of this chapter." 5 C.F.R. § 930.204(a). Moreover, as per 5 C.F.R. § 930.206(a), "[a]n agency may not rate the job performance of an administrative law judge" and as per 5 C.F.R. § 930.206(b) also may not "grant any monetary or honorary award or incentive under 5 U.S.C. [§§] 4502, 4503, or 4504, or under any other authority, to an administrative law judge." Moreover, ALJs may be subject to adverse employment actions "only for good cause established and determined by the Merit Systems Protection Board on the record after opportunity for hearing before the Board."

5 U.S.C. § 7521(a). Administrative patent judges, on the other hand, are subject to the PTO's "independent control of its . . . personnel decisions and processes[,]" which are "vested in" the Director. 35 U.S.C. §§ 1(a), 3(a)(1). The PTO also provides administrative patent judges with "Gain-Sharing Bonuses." PTO, Administrative Patent Judge Recruitment Brochure at 2, https://www.uspto.gov/ip/boards/bpai/ptab_brochure_v2_4_10_14.pdf (last visited Aug. 30, 2017).

Third, ALJs are prohibited from engaging in *ex parte* communications regarding the merits of the proceedings before them. 5 U.S.C. § 557(d)(1)(B). If an ALJ makes or receives such a communication, it must be documented in the public record. 5 U.S.C. § 557(d)(1)(C). In contrast, "non-ALJ agency adjudicators such as the PTAB's [administrative patent judges] . . . are generally not subject to the APA's prohibition of *ex parte* communications with agency officials during and about their hearings." Golden, 65 Duke L.J. at 1682 (internal quotation marks omitted).

Fourth, ALJs "shall be assigned to cases in rotation so far as practicable, and may not perform duties inconsistent with their duties and responsibilities as [ALJs]." 5 U.S.C. § 3105. In contrast, the Director designates administrative patent judges for each 3-member PTAB panel. 35 U.S.C. § 6(c). Moreover, as discussed in detail in Section II, *supra*, the Director is empowered to stack the PTAB panel with additional judges when a 3-judge panel reaches a decision that is contrary to the Director's policy preferences. *See Nidec Motor*, 2017 U.S. Dist. LEXIS 15923, at *17.

For these reasons, the process of adjudication before the PTAB—unlike proceedings before ALJs—is ***not***

"structured so as to assure that the [administrative patent judges] exercise[] [their] independent judgment on the evidence before [them], free from pressures by the parties or other officials within the agency." *See Fed. Mar. Comm'n*, 535 U.S. at 756.

CONCLUSION

Because the statutory design of IPRs does not meet the requirements of the Constitution, this Court should find IPRs to be unconstitutional.

Respectfully submitted,

JAMES HARRINGTON
Senior Vice President and Chief Intellectual Property Counsel
SHIRE PHARMACEUTICALS LLC
95 Hayden Avenue
Lexington, MA 02421

EDGAR H. HAUG
Counsel of Record
NICHOLAS F. GIOVE
RICHARD F. KURZ
JONATHAN A. HERSTOFF
HAUG PARTNERS LLP
745 Fifth Avenue
New York, NY 10151
(212) 588-0800
ehaug@haugpartners.com

Counsel for Amicus Curiae